Original article

Standardized bilateral mesh supported uterosacral ligament replacement – cervico-sacropexy (CESA) and vagino-sacropexy (VASA) operations for female genital prolapse

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Abstract: *Aim*: The treatment of female genital prolapse is often associated by urinary incontinence. Based upon the important role of the uterosacral ligaments as part of the female genital holding apparatus we developed a surgical procedure to replace these ligaments. *Methods*: Women with genital prolapse were operated by means of cervico-sacropexy (CESA) or vagino-sacropexy (VASA). Polyvinylidene fluoride (PVDF) tapes of defined length were used to replace the uterosacral ligaments (USL). The patients were clinically examined at several time intervals after surgery. The data were analysed retrospectively. *Results*: The follow-up period ranged between 4 and 36 months with a median observation time of 20 months. 76 patients were operated for POP-Q stage II-IV using the CESA and VASA techniques. After surgery in all patients POP-Q stage 0 was observed. Before surgery in 66 patients an anterior colporrhaphy was indicated based on a POP-Q stage II of the cystocele. CESA and VASA led to a reduction of the cystocele so that no additional colporrhaphy had to be performed. Before surgery 49 patients were suffering from urgency urinary incontinence symptoms. After surgery 70% of these patients were cured of their incontinence. *Conclusion*: CESA and VASA operations led to an anatomical repair of genital prolapse. In 90% of patients a concomitant cystocele disappeared. CESA and VASA cured urge urinary incontinence and mixed urinary incontinence in 70% of these patients. Since CESA and VASA were standardized with identical steps in every patient these operations can be identically performed by every surgeon.

Keywords: Genital prolapse; Incontinence; Ligaments; USL; PUL.

INTRODUCTION

The treatment of female genital prolapse offers numerous surgical alternatives[1]. In case of uterus prolapse most often a vaginal hysterectomy is performed in combination with a colporrhaphy[2]. In patients with prolapse of the vaginal apex several suspension techniques have been developed which basically fix the prolapsed vaginal apex at different anatomical structures in the pelvis[1]. Because most of these patients have completed their childbearing all of these operations are aimed only to anatomically reconstruct the vagina.

However, all these prolapse operations lead to a high rate of urinary incontinence thereafter. That was demonstrated for sacrocolpopexy (SCP), sacrospinous fixation (SSF) and even for vaginal hysterectomy (VH). The CARE study reported an incontinence rate of more than 80% in previously continent women within 7 years after sacrocolpopexy[3]. In another multicenter trial the "de novo" incontinence rate was lately reported with 25% de novo stress incontinence and 14% urgency already one year after sacrospinous fixation[4]. Furthermore, also vaginal hysterectomy for treatment of uterus prolapse led to the development of urinary incontinence in more than 50% of patients within a few years after surgery[5,6].

Prolapse is caused by a defect of the pelvic "holding apparatus"[7,8]. The uterosacral ligaments (USL) play a critical role in that respect and may cause urinary incontinence as proposed by Petros and Ulmsten[9,10].

Because SCP, SSF and VH do not repair or replace the USL we hypothesized that all these procedures were "unphysiological" and thereby responsible for urinary incontinence. We therefore attempted to develop a surgical procedure which replaced the USL[11]. This bilateral replacement of the USL should lead to an anatomical correction of the prolapse and prevent urinary incontinence.

We now report about the cervico-sacropexy (CESA) and the vagino-sacropexy (VASA) as treatment for female genital prolapse with and without urinary incontinence.

MATERIALS AND METHODS

This study was a retrospective analysis of the outcome of cervico-sacropexy (CESA) and vagino-sacropexy (VASA). Follow-up examinations were performed at 2, 4, 8 and 16 weeks and at yearly intervals after CESA or VASA. Patients who could not come to the institution for a yearly clinical examination had telephone interviews once a year after surgery. A relapse of prolapse was defined as POP-Q stage > I.

Women with symptomatic genital apical prolapse POP-Q stage II, III and IV underwent surgical treatment by means of CESA and VASA between 2012 and 2014 at the Division of Urogynecology, University Hospital of Cologne, Germany. Pelvic organ prolapse was routinely measured according to the POP-Q system[12].

Based on our previous experience with CERESA and VARESA an anterior colporrhaphy was not routinely performed in this study. The indication for a colporrhaphy was therefore made in the operating theatre (OT) during the vaginal examination immediately after CESA or VASA with the patients under general anaesthesia. In this situation the indication for an anterior colporrhaphy was defined when Point Ba was ≥ –1cm. The only exception for that rule was when Point Ba had increased of at least 2 cm compared to the examinations before surgery.

For this purpose POP-Q measurements were performed in the OT under general anaesthesia, with neuromuscular blockades and endotracheal intubation, immediately before and after surgery. A clamp was horizontally fixed at the cervix or the vaginal vault and in order to standardize the measurements the clamp was pulled in the vaginal axis with defined traction of 10 Newton (1 kilogram) controlled by a portable electronic scale (Shenzhen Oway Technology Co., Ltd, Guangdong, China).

Before VASA and under general anaesthesia a vaginal dilator was placed in the vagina in order to stretch the vaginal apex during intra-abdominal suturing of the structure on the vaginal apex.

The augmentation of the uterosacral ligaments was performed using a narrow but open pore sling structure of 4

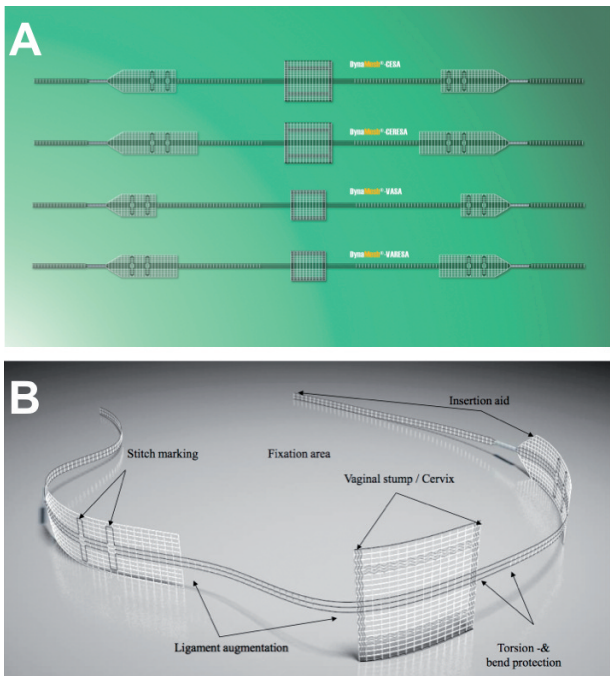

Figure 1A. – The structures for replacement for the uterosacral ligaments have been developed. They differ in length (CESA / CERESA 8.8 cm; VASA / VARESA 9.3 cm) and in the dimension in size of the fixation area.
Figure 1B. – Details of a CESA structure: the stitch markings at the posterior side show where the sutures must be placed. The insertion aid is cut after placement of the structure.

mm width made with high strength PVDF-filaments (Dynamesh CESA, Dynamesh CERESA, Dynamesh VASA and Dynamesh VARESA, FEG Textiltechnik mbH, Aachen, Germany) (Fig. 1A). Compared to the CERESA and VARESA tapes the new "USL-tapes" included the fixation side, thereby preventing an isolated rupture of the structures from the underlying tissue (Fig. 1B). One day before surgery the patients had a bowel cleansing as if for a colonoscopy. Before surgery cephalosporines were administered as a single dose injection. The CESA, CERESA, VASA and VARESA techniques have been described in detail (www.cesa-vasa.com). In summary the two new USL-tapes were fixed at the cervix or at the vaginal stump, pulled beneath the peritoneal fold of the USL on both sides of the pelvis and sutured at the pre-vertebral fascia at S1 and S2 (Fig. 2). After supracervical hysterectomy the anterior fixation area was fixed with 4 non-resorbable sutures

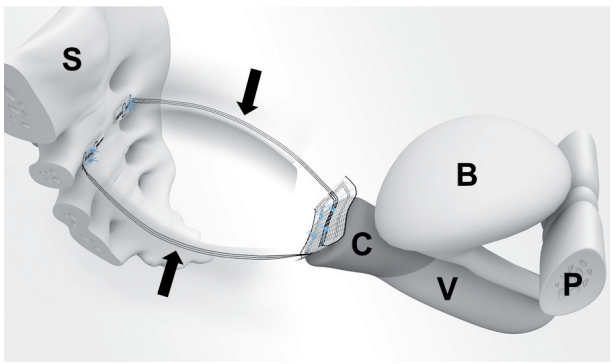

Figure 2. – The drawing shows the placed Dynamesh CESA tape. The tape is sutured with 4 non-resorbable sutures at the cervix (C), led through the peritoneal fold of the USL (black arrows) and sutured at the marked sides of the tape with two sutures to the pre-vertebral fascia on each side of S2 (S); Vagina (V); Bladder (B).

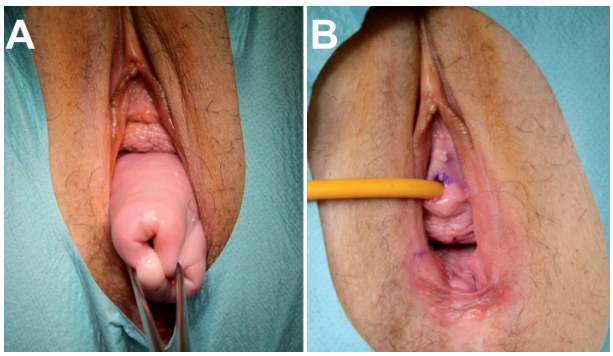

Figure 3. – Partial prolapse of the uterus before surgery.
Figure 3B. – Postoperative view after the CESA operation (note: without anterior colporrhaphy)

at the cervical stump (in VASA and VARESA the respective fixation sites were sutured to the vaginal stump) (Fig. 3A, 4A-D). The presacral fixation sites in front of S1/S2 were prepared (Fig. E). Two non-resorbable fixation sutures were placed in the prevertebral fascia (Fig. 4F). A TVT trocar was placed through the peritoneal fold of the USL to the origin of the USL (Fig. 5A). The insertion aid of the structure was put through the hole of the TVT trocar and the trocar was pulled backwards (Fig. 5B). Thereby the new USL structure was placed in the correct peritoneal fold and sutured (Fig. 5C). The same procedure was identically performed on the left side (Fig. 5D). All insertion sites were peritonealized with resorbable sutures (Fig. 5E, 3B).

The post-void residual urine volume (PVR) was measured by means of ultrasound.

Urinary incontinence (UI) was defined according to the recommendation of the ICS [13]**.** Validated urinary incontinence questionnaires (BBUSQ-22 and ICIQ-UI-SF) were answered before surgery, 4 months and one year after surgery. Cure was defined as the absence of any UI after CESA or VASA.

Patients who were still suffering from urinary incontinence after CESA or VASA were offered a transobturator tape (TOT).

Ethical approval for this study was obtained from the Local Ethics Commission (LEC) of the Faculty (No. 11-016). After 10 and 20 patients the LEC decided on basis of the comparison between these results and the results obtained by CERESA and VARESA (interim analysis) about the further continuation of the study.

Metric variables are presented as mean ± standard deviation (SD), if normally distributed. The Mann-Whitney-U-test was applied for comparisons of independent groups and the Wilcoxon signed rank test for paired samples since most variables were not normally distributed. For categorical data absolute and relative frequencies were calculated and compared by Chi-squared-test or Fisher's exact test. The two-sided significance level was set at 0.01. IBM SPSS Statistics 22 was used for the statistical analyses.

RESULTS

Seventy-six patients were treated by means of CESA and VASA according to the study protocol. Forty-two patients suffering from uterus prolapse underwent surgical treatment by CESA and 34 patients had a vaginal vault prolapse and underwent surgical treatment by VASA. Sixty-four patients suffered from POP-Q stage II prolapse while 12 patients from stage III and IV respectively. The distribution of POP-Q stages II–IV is shown in Table 1 and Figure 6.

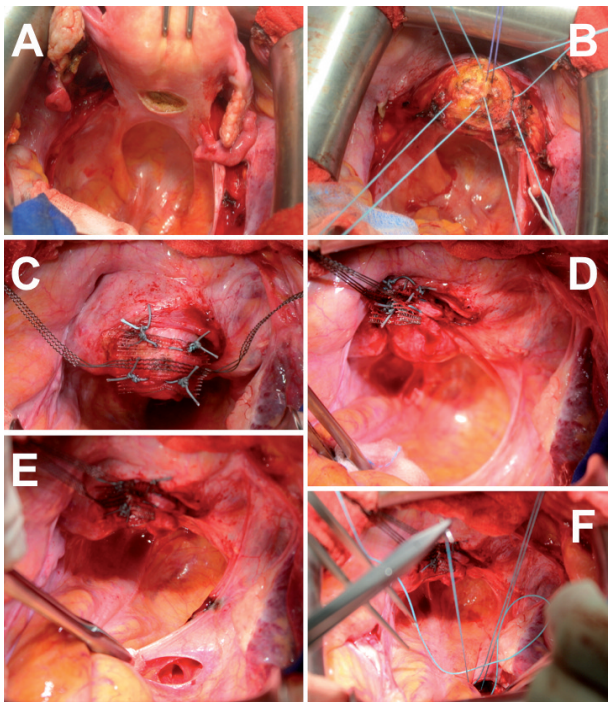

Figure 4. – In CESA the corpus is resected 0.5 cm above the insertion site of the uterosacral ligaments. Therefore, at the start of surgery the level of resection is incised.
Figure 4B. – Four nonresorbable sutures 2-0 are placed at all 4 quadrants of the cervical stump (in the case of VASA, these sutures are placed below and above the scar of the vaginal vault).
Figure 4C. – After placing the CESA (or VASA) tape the sutures are pulled through the net structure between the USL ("bridge") and tied.
Figure 4D. – The end of the USL at the sacrum is defined by pulling the cervix or uterus in the contra lateral direction and pushing the rectum with a swab in the height of S2 in the same direction.
Figure 4E. – The sacral end of the USL is defined and the incision of the peritoneum in front of the sacrum is placed horizontally 0.5 cm above that end. That is usually above the first (S1) or second sacral vertebra (S2).
Figure 4F. – From these incisions the pre-vertebral fascia is prepared. Two nonresorbable sutures 2-0 are placed horizontally in this fascia at each side of the rectum. Care has to be taken to avoid injuries of the peritoneal fold of the USL.

Four months after CESA and VASA 76 patients (100%) had POP-Q stage 0. Point C was in all patients between –6 cm and –10 cm (Fig. 6). The total vaginal length of the patients was between 8 cm to 13 cm. After the apical fixation by CESA and VASA we found a reduced size of the cystoceles.

Before surgery, in 50 patients (66%) Point Aa was ≥ –1 cm, in 66 patients (87%) Point Ba was ≥ –1cm. After CESA and VASA Point Aa was relocated to –3 cm in 48 patients (63%) and in 25 patients (33%) to –2 cm. Point Ba was also relocated to –3 cm in 47 patients (62%) and in 24 patients (32%) to –2 cm (Fig. 6).

During the immediate post-CESA / VASA vaginal examination in the OT in none of the 76 patients an indication for an anterior colporrhaphy was given. After 4 months of follow-up 5 patients (7%) required further surgical treatment by anterior colporrhaphy. So far none of the remaining patients needed a further repair. No de-novo urinary incontinence was observed in the pre-operative continent women. The anatomical results remained identical during the follow-up period.

Before surgery 51 patients (67%) complained about the sensation of incomplete bladder emptying and had elevated

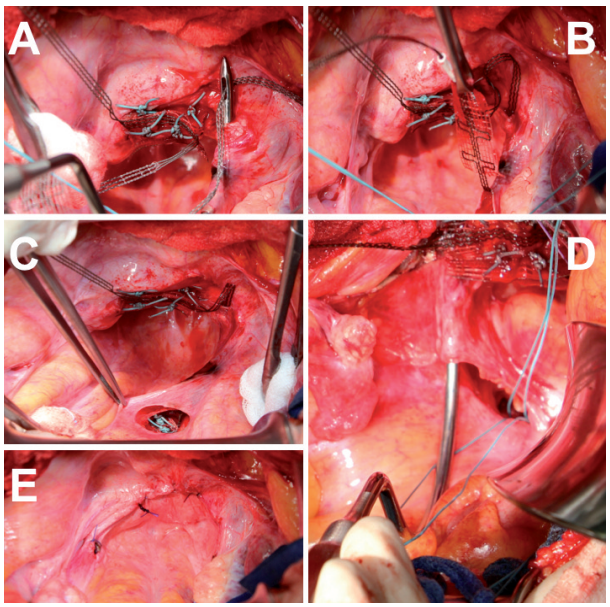

Figure 5A. – A small trocar, as usually used for a TVT placement, is pulled through the right peritoneal fold of the USL from the back to the base. The insertion aid of the tape is pulled through the hole at the top.
Figure 5B. – The trocar, guiding the tape, is pulled backwards to the sacrum.
Figure 5C. – The previously-placed sutures are pulled through the marked fixation sides at the tape, the insertion aid is cut and the sutures are tied. That is done on both sides of the rectum.
Figure 5D. – A small trocar is pulled through the left peritoneal fold of the USL from the back to the base.
Figure 5E. – The incisions at the sacrum are closed with resorbable sutures 4-0 at both sides. Thereafter in CESA the cervical stump is peritonealized with the bladder and Douglas peritoneum.

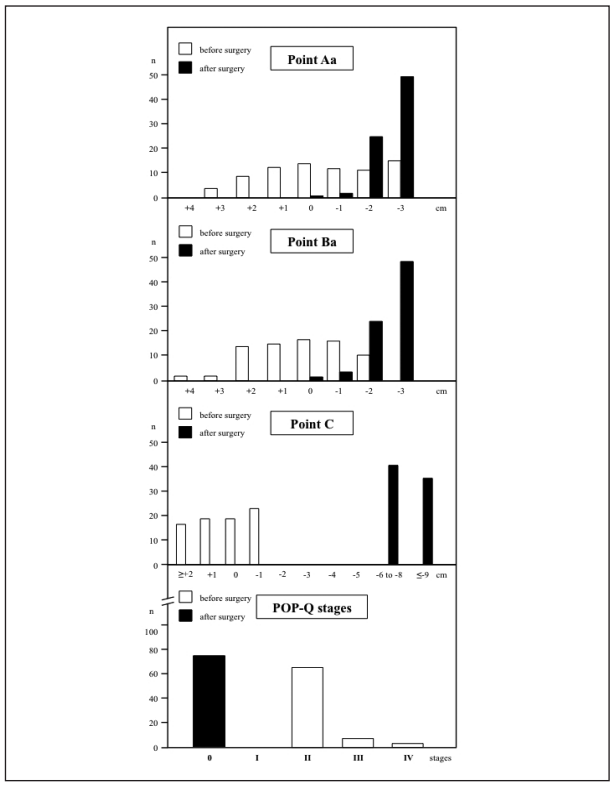

Figure 6. – Distribution of POP-Q Points Aa, Ba, C and stages of the 76 patients in the study before (white columns) and after surgery (black columns). Note the interrupted scale for POP-Q stages.

TABLE 1. Baseline clinical parameters of the 76 women in the study at the time of surgery.

Parameter	Total cohort (n=76)	CESA group (n=42)	VASA group (n=34)	p-value
Age at surgery, years, mean, ±SD (range)	64.9 ± 12.8 (31 - 92)	63.7 ± 13.8 (31 - 89)	67.0 ± 10.8 (50 - 92)	NS
Body mass index, mean, ±SD (range)	25.1 ± 3.9 (16.7-33.3)	24.6 ± 4.0 (16.7-30.3)	25.9 ± 3.8 (19.8-32.8)	NS
Parity, no. (%)				
Nulliparous	9 (11.9)	6 (14.3)	3 (8.8)	NS
Primiparous	16 (21.0)	10 (23.8)	4 (11.8)	
Multiparous	51 (67.1)	26 (61.9)	27 (79.4)	
Menopausal status, no. (%)				
Premenopausal	11 (14.5)	9 (21.4)	2 (5.9)	NS
Postmenopausal	65 (85.5)	33 (78.6)	32 (94.1)	
POP-Q stages, no. (%)				
Stage 0	0 (0)	0 (0)	0 (0)	NS
Stage I	0 (0)	0 (0)	0 (0)	
Stage II	60 (79)	35 (83)	25 (74)	
Stage III	13 (17)	5 (12)	8 (24)	
Stage IV	3 (4)	2 (5)	1 (2)	

NS, not significant.

TABLE 2. Urinary incontinence status before and after CESA (cervico-sacropexy) and VASA (vagino-sacropexy).

	CESA group (n=42) no. / total no. (%)			VASA group (n=34) no. / total no. (%)		
Type of urinary incontinence	before surgery	after surgery	p-value	before surgery	after surgery	p-value
Overall urinary incontinence	24 / 42	6 / 42	<0.01	25 / 34	9 / 34	<0.01
Mixed urinary incontinence (MUI)	24 / 24 (100)	6 / 24 (25)	<0.01	25 / 25 (100)	9 / 25 (36)	<0.01
Urgency urinary incontinence (UUI)	0 / 24 (0)	0 / 24 (0)	–	0 / 25 (0)	0 / 25 (0)	–
Stress urinary incontinence (SUI)	0 / 24 (0)	0 / 24 (0)	–	0 / 25 (0)	0 / 25 (0)	–

Urinary incontinence status before and 4 months after CESA (cervico-sacropexy) and VASA (vagino-sacropexy). No de novo UUI or SUI were noted.

PVR. After CESA and VASA all patients (100%) showed adequate bladder emptying.

According to the validated questionnaires 49 patients (65%) were suffering from UI before CESA and VASA. All of these patients had urgency urinary incontinence (UUI) and stress urinary incontinence (SUI) symptoms and these were defined according to their urinary incontinence as mixed urinary incontinence (MUI).

In 18 of the 24 (75%) patients who were operated upon CESA and 16 of the 25 (64%) patients who were operated by the VASA technique complete UI was re-established. Thereby 34 (70%) of the 49 incontinent patients were successfully treated (cured) by CESA / VASA surgery. After the 4-months examination 15 patients were still urinary incontinent. 11 of these patients agreed to a TOT. All 6 VASA patients and all 5 CESA patients were cured of their UI thereafter. Thereby in 45 out of 49 patients continence was restored by the combined treatment by CESA / VASA and TOT (92%) (Table 2).

The follow-up period ranged between 4 and 36 months with a median observation time of 20 months. During that time 4 patients in the VASA group and one patient in the CESA group developed a cystocele (point Ba > –1 cm) 4 months after surgeries and needed an anterior colporrhaphy. No change of the continence status was observed. No mesh erosion was detected. No rupture of the fixation sides from the underlying cervix or vaginal stump was found by postoperative ultrasound examinations or by new clinical complaints.

During this study no major side effects were observed. The ureters were never injured. The hypogastric nerves were always visualized and injury was avoided.

DISCUSSION

During the last 40 years several changes in the view of the uterovaginal suspension and new insights in the pathophysiology of pelvic organ prolapse (POP) continued to emerge. In 1976 Richardson s research emphasised on breaks and tears of the endopelvic fascia which led to side-specific operations[14].

In 1992 and 1993 the examinations of DeLancey et al. then directed the interests towards the different levels of the pelvic floor and especially the apical support (uterosacral cardinal ligament complex)[7,8]. The sacrospinous fixation was reborn and the laparoscopical sacro-colpopexy was[15].

In 1993 Petros and Ulmsten hypothesized the association between genital prolapse and UI. According to their Integral Theory the repair of the USL and the pubourethral ligaments (PUL) should cure UI[10]. However, this paradigm shift was not unequivocally accepted because several methods of apical fixation did not lead to a cure of UUI. Especially the long-term results of sacrocolpopexy were nearly contradicting this hypothesis. The CARE study demonstrated that already two years after sacrocolpopexy 66% of patients had developed UI and 59% of patients in the treatment arm of the study were suffering from UI even after a prophylactic Burch operation[16]. The results of the unilateral sacrospinous fixation were in the same range[4]. The latest report of the CARE study reported an even higher rate after 7 years of 80% urinary incontinent women after SCP[3].

The outcome of the bilateral replacement of the USL by CESA and VASA operations led us to assume that this kind of replacement surgery led to a “physiological” repair and a restoration of function[11].

The anatomical results after VASA and CESA according to our intentions could be described as POP-Q stage 0. CERESA or VARESA were only performed in patients with additional fecal incontinence (data not included).

Siddique et al. had published a physiological length of 8.8 cm. Therefore, we decided to take that length for the USL structures for CESA[17]. For VASA we considered that the vagina was shortened by hysterectomy and deliberately decided to lengthen these structure to 9.3 cm.

According to the obstetrical textbooks and the MRT measurements by Rizk *et al*. the distances between the bony structures of the small pelvis are identical in all women irrespective of weight, parity or racial derivation[18]. Therefore, the identical lengths of the structures were used in all women operated by CESA or VASA.

This is one of the main aspects why these operations were called “standardized” because the localization of the tapes, the fixation sides and the lengths were defined to be identical in all patients!

After CESA or VASA a “cystocele” disappeared in 93% of all patients. We therefore abstained from immediate anterior colporrhaphy in these patients. During follow-up only 2 women developed a recurrent cystocele which needed surgical repair.

We expected a good anatomical repair of the apical fixation by CESA and VASA; however, we were excited to follow the outcome on urinary incontinence.

70% of the incontinent patients with prolapse and UI

were cured just by CESA and VASA. De novo UI was not observed in the other patients after a median follow-up of 20 months. These were important observations because they indicated a striking difference to the above mentioned side-effects of SCP, SSF or VH.

We hypothesize that this was caused by our intention of a "physiological" replacement of the USL considering the bilateral course, the length, the anatomical position and probably the vectors in the small pelvis. These effects on UI definitively need further evaluation.

The CESA and VASA surgical procedures are safe in the hands of a pelvic surgeon. The points of risk – ureter, veins and arteries, hypogastric nerve – are all clearly visible during surgery. It is important to note that no major adverse side effects were observed during CESA or VASA in this study. After surgery the bulging symptoms had totally disappeared in all patients. None of the patients reported dyspareunia.

The CESA and VASA operations imitate the physiological structures in the female small pelvis as close as possible. The operations were standardized so that every pelvic surgeon can perform the operation in an identical way. The length of the implanted tapes was identical in every patient.

The standardized CESA and VASA operations offer a great chance to compare the outcome of different centres worldwide. New operations techniques can be tested and be compared with the standardized CESA and VASA operations. That will definitively contribute to a better understanding of pelvic floor disorders and UI, which on the long-term perspective aims to cure patients suffering from these disorders.

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DISCLOSURES

W. Jaeger receives an honorarium for teaching courses and giving lectures from the FEG Textiltechnik mbH, Aachen, Germany. S. Ludwig receives reimbursement for travel expenses for teaching courses outside of Cologne, Germany. M. Stumm and P. Mallmann report no conflict of interests.

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